

Anderson et al. - U.S. Patent Appl. No. 09/576,424

I. AMENDMENT TO THE DRAWINGS

Please replace Figure 5a as originally filed with amended Figure 5A submitted herewith.

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III. REMARKS

Preliminary Remarks

Reconsideration and allowance of the present application based upon the following amendment and remarks are respectfully requested. Claims 11, 12, 19, 20, and 27-55 are currently pending in this application. Claims 11, 12, 19, 20, 27-37, 39-48, and 50-55 have been found allowable. Claims 36-38 and 49 are still at issue. This response is timely filed with a three-month extension of time.

In paragraph 5 of the official action, the examiner objected to claims 32 and 33 because the claims should recite "anti-CD54 antibody", "anti-CD11 antibody", "anti-CD11a antibody", and anti-IL-1 antibody" for clarity. The applicants have amended claims 32 and 33 by inserting the word "antibody" after the words of the appropriate molecules (*i.e.*, anti-CD54, anti-CD11, anti-CD11a, and anti-IL-1).

The applicants hereby submit a replacement sheet of Figure 5A that is labeled "Replacement Sheet" along with a marked-up copy of Figure 5A as required by 37 C.F.R. §121(d). In Figure 5A, the applicants have (1) replaced "V" (valine) at amino acid position no. 23 with an "A" (alanine); (2) replaced "T" (thymine) at corresponding nucleotide position no. 68 with a "C" (cytosine); (3) replaced "S" (serine) at amino acid position no. 138 with a "T" (threonine); and (4) replaced "T" (thymine) at corresponding nucleotide position no. 412 with an "A" (adenine). The applicants submit that replacement Figure 5a does not constitute new matter because support for the correct light chain 16c10 nucleotide and amino acid sequences can be found in the ATCC deposit, which was deposited with ATCC on May 29, 1996 and this information can be found in the specification at page 61, lines 10-17 of the specification (as submitted by amendment November 4, 2004). Copies of the replacement drawing Figure 5A for the above-identified application are attached hereto, in compliance with 37 C.F.R. § 1.85 and does not constitute new matter.

Amended claims 12 and 28 are directed to the method of claim 11 or 27, wherein said anti-CD80 antibody is a human monoclonal antibody or a chimeric or humanized antibody comprising constant regions derived from human constant regions. Support for amended claims 12 or 28 can be found throughout the specification, for example page 39 lines 1 and 2 and 7-14. The applicants do not intend by these or any amendments to abandon subject

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matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

Patentability Remarks

Rejection Pursuant to 35 U.S.C. §132

In paragraph 3 of the official action, the examiner objected to amended SEQ ID NOS: 9 and 10 and the informal replacement of Figure 5A for allegedly submitting new matter. The examiner, in the interest of clarifying the record, would like the applicants to submit a verified statement from a person to corroborate the fact that the corrected sequence of 16C10 light chain antibody is indeed the correct sequence of 16C10 light chain identified in the application and the same as the nucleotide/amino acid sequence of ATCC Deposit Accession No. HB-12119. The examiner further states that the provision of the appropriate declaration would obviate this objection as well as the rejection under 35 U.S.C. §112, first paragraph.

In response, the applicants submit a declaration pursuant to 37 C.F.R. §1.132, which is executed by Mitchell Reff, Ph.D. and attests to the fact that the amended 16C10 light chain sequences corrected July 26, 2005 are identical to the nucleotide sequence and amino acid sequence of the express 16C10 antibody by the hydridoma deposited with the American Type Culture Collection (ATCC Deposit Account No. HB-12119 deposited on May 29, 1996). Dr. Reff states that the corrected sequence of the 16C10 light chain antibody is indeed the correct sequence of the 16C10 light chain antibody specifically identified in the application as originally filed. Accordingly, the applicants submit no new matter has been added to the disclosure through amended SEQ ID NOS: 9 and 10 and informal replacement figure for Figure 5A. In view of the foregoing remarks and corroborative declaration, the applicants respectfully submit that the objection of amended SEQ ID NOS: 9 and 10, and replacement Figure 5a, for allegedly containing new matter, has been overcome and should be withdrawn.

Rejection Pursuant to 35 U.S.C. §112, first paragraph

In paragraph 4 of the official action, the examiner rejected claims 38 and 49 under 35 U.S.C. §112, first paragraph, for allegedly lacking proper written descriptive support from the specification. Specifically, the examiner alleged that the specification, as originally filed, does not provide support for the invention of now claimed SEQ ID NOS: 9 and 10. The examiner has acknowledged that the applicants' remarks that the nucleotide and amino acid sequence of the ATCC Deposit Accession No. HB-12110 is the same as the sequence filed in

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the substitute Sequence Listing. The examiner requests, however, that a verified statement from a person in a position to corroborate the fact that the corrected sequences of the 16C10 light chain antibody are indeed the correct sequences of the 16C10 light chain antibody specifically identified in the application as filed.

In response, the applicants direct the examiner's attention to their remarks with respect to the objection under 35 USC § 132. Based upon those remarks, the applicants submit that the rejection of claims 38 and 49 under 35 U.S.C. §112, first paragraph for allegedly lacking written descriptive support, has been overcome and should be withdrawn.

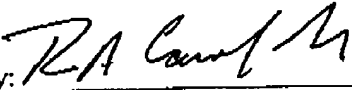
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IV. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action such action is hereby solicited. If any point remains at issue which the examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

Respectfully submitted,

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Marked-up version of drawing

Frame 1 M R V P A O L L G L L L L W L P G A R
 ATG AGG GTC CCC GCT CAG CTC CTG GGG CTC CTG CTC TGG CTC CCA GGT GCA CGA
 9 18 27 36 45 54
 C E S A L T J P P S V S G A P G O K V T I
 TGT GAG TCT GTC CTG ACA CAG CCG CCC TCA GTG TCT GGG GCC CCA GGG CAG AAG GTC ACC ATC
 63 72 81 90 99 108 117
 S C T G S T S N I G G Y D L H W Y O O L P
 TCG TGC ACT GGG AGC ACC TCC AAC ATT GGA GGT TAT GAT CTA CAT TGG TAC CAG CAG CTC CCA
 126 135 144 153 162 171 180
 G T A P K L L I Y D I N K R P S G I S D R
 GGA TCG GCC CCC AAA CTC CTC ATC TAT GAC ATT AAC AAG CGA CCC TCA GGA ATT TCT GAC CGA
 189 198 207 216 225 234 243
 F S G S K S G T A A S L A I T G L O T E D
 TTC TCT GGC TCC AAG TCT GGT ACC GCG GCC TCC CTG GCC ATC ACT GGG CTC CAG ACT GAG GAT
 252 261 270 279 288 297 306
 E A D Y Y C O S Y D S S L N A O V F G G G
 GAG GCT GAT TAT TAC TGC CAG TCC TAT GAC AGC AGC CTG AAT GCT CAG GTA TTC GGA GGA GGG
 315 324 333 342 351 360 369
 T R L T V L G O P K A A P T V T L F P P S
 ACC CGG CTG ACC GTC CTA GGT CAG CCC AAG GCT GCC CCC TCG GTC ACT CTG TTC CCG CCC TCC
 378 387 396 405 414 423 432
 S E E L O A N K A T L V C L I S D F Y F G
 TCT GAG GAG CTT CAA GCC AAC AAG GCC ACA CTG GTG TGT CTC ATA AGT GAC TTC TAC CCG GGA
 441 450 459 468 477 486 495
 A V T V A W K A D S S P V K A G G V E T T T
 GCC GTG ACA GTG GCC TCG AAG GCA GAT AGC AGC CCC GTC AAG GCG GGA GTG GAG ACC ACC ACA
 504 513 522 531 540 549 558
 P S K O S N N K Y A A S S Y L S L T A C P E O
 CCC TCC AAA CAA AGC AAC AAC AAG TAC GCG GCC AGC AGC TAC CTG AGC CTG ACG CCT GAG CAG
 567 576 585 594 603 612 621
 W K S H R S Y S C O V T H E G S T V E K T
 TGG AAG TCC CAC AGA AGC TAC AGC TGC CAG GTG ACG CAT GAA GGG AGC ACC GTG GAG AAG ACA
 630 639 648 657 666 675 684
 V A P T E C S
 GTG GCC CCT ACA GAA TGT TCA TGA
 693 702 711

FIG. 5A